

Claim Listing:

Claims 1 – 120. (Canceled).

121. (Previously Presented) A neurological control system for modulating the activity of at least one nervous system component, the neurological control system comprising:

at least one intracranial stimulating electrode, each constructed and arranged to deliver a neural modulation signal to at least one nervous system component;

at least one sensor, each constructed and arranged to sense at least one parameter that comprises at least one of physiologic values and neural signals, which is indicative or predictive of a seizure; and

a stimulating and recording unit constructed and arranged to generate said neural modulation signal based upon a neural response sensed by said at least one sensor in response to a previously delivered neural modulation signal.

Claim 122. (Canceled)

123. (Original) The system of claim 121, wherein said stimulating and recording unit generates said neural modulation signal in accordance with predetermined treatment parameters to treat the seizure.

124. (Previously Presented) The system of claim 121, wherein said stimulating and recording unit comprises:

a signal processor constructed and arranged to process said neural response to determine a neural system state; and

a control module for adjusting said neural modulation signal based upon said neural system state.

125. (Previously Presented) The system of claim 124, wherein each of said at least one sensor generates one or more neural response signals, and wherein said stimulating and recording unit further comprises:

a signal conditioner, interposed between said at least one sensor and said signal processor, constructed and arranged to modify said one or more neural response signals appropriately for said signal processor.

126. (Previously Presented) The system of claim 125, wherein said signal conditioner comprises:

at least one amplifier, each constructed and arranged to amplify said one or more neural response signals generated by an associated one of said at least one sensor; and

at least one signal filter, each constructed and arranged to filter said one or more amplified neural response signals generated by an associated one of said at least one amplifier.

127. (Previously Presented) The system of claim 126, wherein said at least one signal filter performs at least one of lowpass filtering, highpass filtering, bandpass filtering and notch filtering of said one or more amplified neural response signals.

128. (Previously Presented) An apparatus for modulating the activity of at least one nervous system component, said system comprising:

means for monitoring parameters that are indicative or predictive of a seizure;

means for delivering neural modulation signals to said nervous system component when the means for monitoring indicate or predict the onset of the seizure;

means for sensing a neural response to said neural modulation signals; and

controller means for modulating parameters of a subsequent neural modulation signal based on the sensed neural response to a previously delivered neural modulation signal.

129. (Previously Presented) The apparatus of claim 128, wherein said delivery means comprises means for generating said neural modulation signals, said generating means comprises:

signal conditioning means for conditioning said sensed neural response signals, said conditioning including but not limited to at least one of amplification, lowpass filtering, highpass filtering, bandpass filtering, notch filtering, root-mean square calculation, envelope determination, and rectification; and

wherein said sensing means comprises signal processing means for processing said conditioned sensed neural response signals to determine neural system states.

Claims 130-132. (Canceled).

133. (Previously Presented) The apparatus of claim 128, wherein said means for delivering neural modulation signals to said nervous system component includes electrodes

implemented into at least one of the globus pallidus internus (GPi), including globus pallidus internus internal segment (GPi,i) and globus pallidus internus external segment (GPi,e), globus pallidus externus (GPe), ventral medial (Vim) thalamic nucleus, other portion of the thalamus, subthalamic nucleus (STN), caudate, putamen, other basal ganglia components, cingulate gyrus, other subcortical nuclei, nucleus locus ceruleus, pedunculopontine nuclei of the reticular formation, red nucleus, substantia nigra, other brainstem structure, cerebellum, internal capsule, external capsule, corticospinal tract, pyramidal tract, ansa lenticularis, white matter tracts, motor cortex, premotor cortex, supplementary motor cortex, other motor cortical regions, somatosensory cortex, other sensory cortical regions, Broca's area, Wernicke's area, other cortical regions, other central nervous system structure, other peripheral nervous system structure, other neural structure, sensory organs, muscle tissue, or other non-neural structure.

Claim 134. (Canceled)

135. (Previously Presented) The apparatus of claim 128, wherein said means for sensing a neural response includes at least one of accelerometers, electromyography electrodes, acoustic sensors, intracranial electrodes, electroencephalography electrodes, and peripheral nerve electrodes.

136. (Previously Presented) The apparatus of claim 128, wherein said means for sensing a neural response includes a weighted aggregate of processed signals derived from at least one of accelerometers, electromyography electrodes, acoustic sensors, intracranial electrodes, electroencephalography electrodes, and peripheral nerve electrodes.

137. (Previously Presented) The apparatus of claim 129, wherein said means for generating a neural modulation signal employs a control law using as input signals derived from at least one of accelerometers, electromyography electrodes, acoustic sensors, intracranial electrodes, electroencephalography electrodes, and peripheral nerve electrodes.

138. (Previously Presented) The apparatus of claim 129, wherein said means for generating a neural modulation signal employs a control law using as input a weighted aggregate of professed signals derived from at least one of accelerometers, electromyography electrodes, acoustic sensors, intracranial electrodes, electroencephalography electrodes, and peripheral nerve electrodes.

Claims 139. – 149. (Canceled).

150. (Previously Presented) A system for neural modulation in the treatment of disease, comprising:

- a system enclosure, in mechanical communication with a calvarium;
- a control circuit positioned within said system enclosure and in electronic communication with a signal processor;
- an output stage circuit in electronic communication with said control circuit;
- a stimulating electrode array, in electronic communication with said output circuit;
- an intracranial catheter that is attached to said stimulating electrode array; and
- a microelectrode attached to a microelectrode shaft which is positioned along a longitudinal axis of said intracranial catheter.

Claims 151. – 152. (Canceled).

153. (Previously Presented) A system as in claim 150, wherein said intracranial catheter includes at least one microelectrode tunnel for receiving said microelectrode shaft.

154. (Previously Presented) A system as in claim 150, said system enclosure comprising at least one intracranial catheter port.

155. (Original) A system as in claim 154, said intracranial catheter port positioned at the center of said system enclosure.

156. (Original) A system as in claim 155, said intracranial catheter port positioned at the periphery of said system enclosure.

157. (Previously Presented) A system as in claim 150, said system enclosure including a catheter recess.

158. (Previously Presented) A system as in claim 157, said catheter recess comprising means for establishing contact between said system enclosure and said intracranial catheter.

159. (Original) A system as in claim 150, further comprising catheter stabilization means.

160. (Previously Presented) A system as in claim 159, wherein said catheter stabilization means comprises a catheter mount ball.

161. (Previously Presented) A system as in claim 160, wherein said catheter mount ball comprises a catheter ball channel.

162. (Previously Presented) A system as in claim 159, wherein said catheter stabilization means comprises a catheter insertion mount.

163. (Previously Presented) A system as in claim 162, wherein said catheter insertion mount comprises a catheter mount system enclosure attachment means.

164. (Previously Presented) A system as in claim 162, wherein said system enclosure comprises a system enclosure catheter mount attachment means.

165. (Previously Presented) A system as in claim 159, wherein said catheter stabilization means comprises a catheter locking mechanism.

166. (Previously Presented) A system as in claim 165, wherein said catheter locking mechanism comprises a compressible material.

167. (Previously Presented) A system as in claim 166, wherein said compressible material is compressed against said intracranial catheter.

168. (Previously Presented) A system as in claim 165, wherein said catheter locking mechanism comprises a catheter mount ball locking screw.

169. (Original) A system as in claim 168, wherein said catheter mount ball locking screw provides force to compress said catheter locking mechanism.

170. (Original) A system as in claim 150, further comprising at least one electrode contact.

171. (Original) A system as in claim 170, wherein said electrode contact is in mechanical connection to said system enclosure.

172. (Previously Presented) A system as in claim 170, wherein said electrode contact is contained within a catheter recess.

173. (Previously Presented) An intracranial catheter for use in the treatment of disease, comprising at least one stimulating electrode and at least one microelectrode,

wherein said microelectrode is attached to a microelectrode shaft which is positioned along the longitudinal axis of said intracranial catheter.

Claims 174. (Canceled).

175. (Previously Presented) An intracranial catheter as in claim 173, wherein said microelectrode is attached to said microelectrode shaft which is parallel to the longitudinal axis of said intracranial catheter.

176. (Original) An intracranial catheter as in claim 173, wherein said microelectrode is removable.

Claim 177. (Canceled).

178. (Previously Presented) A system as in claim 150, wherein said system comprises a multiplicity of intracranial catheters.

179. (Previously Presented) A system as in claim 150, further comprising a multiplicity of intracranial catheters, wherein elements of said stimulating electrode array are mechanically attached to at least one of said intracranial catheters.

Claim 180. (Canceled).

181. (Previously Presented) A system as in claim 150, said stimulating electrode array comprising a conducting film mechanically attached to said intracranial catheter.

182. (Previously Presented) A system as in claim 150, said stimulating electrode array comprising a conducting layer deposited on said intracranial catheter.

Claims 183. – 193. (Canceled).

194. (Previously Presented) An intracranial catheter for use in the treatment of disease, the intracranial catheter comprising at least one stimulating electrode and at least one microelectrode, wherein said microelectrode is attached to a microelectrode shaft which is parallel to a longitudinal axis of said intracranial catheter.

195. (Previously Presented) The intracranial catheter as in claim 194, wherein said microelectrode is removably coupled to said at least one stimulating electrode.

196. (Previously Presented) The intracranial catheter as in claim 194, wherein said at least one stimulating electrode is disposed around an outer surface of said intracranial catheter.

197. (Previously Presented) The intracranial catheter as in claim 194, wherein said at least one stimulating electrode comprises a plurality of stimulating electrodes, the plurality of stimulating

electrodes disposed around an outer surface of said intracranial catheter and spaced longitudinally along a length of the intracranial catheter.

198. (Previously Presented) The intracranial catheter as in claim 194, wherein said intracranial catheter comprises a microelectrode channel for receiving the microelectrode shaft.

199. (Previously Presented) The intracranial catheter as in claim 194, wherein a distal tip of said microelectrode is configured to be positionable distal of a distal tip of the intracranial catheter.

200. (Previously Presented) The intracranial catheter as in claim 194, wherein said microelectrode is configured to record single cell activity during advancement of said intracranial catheter through a patient's brain.

201. (Canceled).

202. (Currently Amended) The method of claim 204212, further comprising storing data in a memory that is reflective of the at least one extracted parameters, wherein the memory is implanted in the patient's body.

203. (Previously Presented) The method of claim 202, comprising transcutaneously transmitting the stored data from the memory that is implanted in the patient's body to a communication module that is external to the patient's body.

204. (Currently Amended) The method of claim 204212, wherein the one or more signals comprise brain activity signals and wherein the patient's response comprises a brain activity response.

205. (Previously Presented) The method of claim 204, wherein monitoring the patient's response comprises extracting the at least one parameter that is predictive of the future symptomatology from the brain activity response and comparing the extracted at least one brain activity response parameter to at least one clinician programmed reference parameter.

206. (Previously Presented) The method of claim 205, wherein extracting the at least one parameter and comparing the at least one brain activity response parameter to the at least one clinician programmed reference parameter are performed in a unit that is implanted in the patient's body.

207. (Previously Presented) The method of claim 206, wherein the unit is implanted intracranially in the patient's body.

208. (Currently Amended) The method of claim 201212, wherein the at least one extracted parameter comprises parameters of an EEG signal.

209. (Previously Presented) The method of claim 208, wherein the at least one extracted parameter comprises at least one of a peak-to-valley times, valley-to-peak times, positive phase amplitudes, and negative phase amplitudes of the EEG signal.

210. (Previously Presented) The method of claim 208, wherein the at least one extracted parameter comprises a peak-to-valley times, a valley-to-peak times, a positive phase amplitudes, and a negative phase amplitudes of the EEG signal.

211. (Currently Amended) The method of claim 201212, wherein monitoring the patient's response to the neural modulation signal comprises determining if undesirable brain activity is present.

212. (Currently Amended) A method of managing a neurological or psychiatric disease state, the method comprising:

measuring one or more signals from a patient's brain;

extracting at least one parameter from the one or more signals that are predictive of future symptomatology of a neurological or psychiatric disease;

delivering a neural modulation signal to the patient when the one or more signals predict an onset of the symptomatology;

monitoring a patient's response to the neural modulation signal;

The method of claim 201, further comprising processing the patient's response to the neural modulation signal to derive at least one parameter of ~~the~~ a subsequent neural modulation signal; and

delivering the subsequent neural modulation signal to the patient if the response to the neural modulation signal indicates that the subsequent neural modulation signal is needed.

213. (Currently Amended) The method of claim 201212, wherein the subsequent neural modulation signal is needed if a desired change in brain activity is not achieved with the neural modulation signal.

214. (Currently Amended) The method of claim 201~~212~~, wherein at least one of the neural modulation signal and subsequent neural modulation signals comprise a pulse train of waveforms.

215. (Previously Presented) The method of claim 214, wherein the pulse train of waveforms comprise one or more bursts of waveforms.

216. (Previously Presented) The method of claim 215, wherein the one or more bursts each comprise one or more charge-balanced biphasic stimulus pulses.

217. (Previously Presented) The method of claim 215, wherein the pulse train of waveforms comprise a plurality of bursts of charge-balanced biphasic stimulus pulses.

218. (Canceled).

219. (Currently Amended) The method of claim 248~~220~~, further comprising:
coupling at least one electrode to the vagus nerve of the patient, wherein the electrical stimulation is delivered to the electrode coupled to the vagus nerve of the patient; and
intracranially implanting one or more electrodes, wherein the one or more electrodes are used to monitor the brain activity response to the electrical stimulation to the vagus nerve.

220. (Currently Amended) A method, comprising:
delivering electrical stimulation to a vagus nerve of a patient;
monitoring a brain activity response to the electrical stimulation to the vagus nerve; and
delivering a subsequent electrical stimulation to the patient if brain activity response indicates that the subsequent electrical stimulation is needed.

The method of claim 218, wherein monitoring the brain activity response comprises identifying action potentials in individual neurons in the patient's brain.

221. (Previously Presented) The method of claim 220, wherein identifying action potentials in individual neurons in the patient's brain is performed using one or more microelectrodes.

222. (Currently Amended) The method of claim 248~~220~~, wherein monitoring the brain activity response comprises monitoring aggregate activity from groups of neurons.

223. (Currently Amended) The method of claim ~~218~~²²⁰, wherein monitoring the brain activity response comprises extracting parameters from one or more signals that are indicative of electrical activity of groups of neurons in the patient's brain.

224. (Currently Amended) The method of claim ~~218~~²²⁰, further comprising, prior to delivering electrical stimulation to the vagus nerve of a patient,;

measuring one or more signals from the patient's brain;

extracting one or more parameters from the one or more signals that are predictive of future symptomatology,

wherein the electrical stimulation is delivered to the vagus nerve of the patient only when the future symptomatology is predicted.

225. (Currently Amended) The method of claim ~~218~~²²⁰, further comprising storing the patient's response to the electrical stimulation signal in a memory device.

226. (Currently Amended) A method, comprising:

delivering electrical stimulation to a vagus nerve of a patient;

monitoring a brain activity response to the electrical stimulation to the vagus nerve;

The method of claim 218, further comprising deriving parameters of the^a subsequent electrical stimulation signal from the brain activity response to the electrical stimulation signal; and delivering the subsequent electrical stimulation to the patient if brain activity response indicates that the subsequent electrical stimulation is needed.

227. (Canceled).

228. (Currently Amended) The method of claim ~~227~~²³¹, wherein at least one of the first and second neural modulation signal comprises one or more electrical stimulation waveforms.

229. (Previously Presented) The method of claim 228, wherein the one or more electrical stimulation waveform comprises one or more charge-balanced biphasic waveforms.

230. (Currently Amended) The method of claim ~~227~~²³¹, wherein at least one of the first and second neural modulation signals is delivered to a peripheral nerve.

231. (Currently Amended) A method of managing epilepsy, comprising:

monitoring parameters of a patient's brain activity to predict an onset of a seizure;

delivering a first neural modulation signal to the patient when the monitored parameters of a patient's brain activity indicate undesirable brain activity that is predictive of the onset of a seizure;
monitoring a patient's brain activity response after delivering the first neural modulation signal; and

delivering a second neural modulation signal to the patient if the monitored brain activity response indicates that said patient's brain activity is undesirable.

The method of claim 227, wherein monitoring the patient's brain activity response comprises identifying action potentials in individual neurons in the patient's brain.

232. (Previously Presented) The method of claim 231, wherein identifying action potentials in individual neurons in the patient's brain is performed using one or more microelectrodes.

233. (Currently Amended) The method of claim 227~~231~~, wherein monitoring the patient's brain activity response comprises monitoring aggregate activity from a population of neurons.

234. (Currently Amended) The method of claim 227~~231~~, wherein monitoring parameters of the patient's brain activity response comprises:

monitoring one or more signals from a nervous system component; and
extracting parameters from the one or more signals that are indicative of electrical activity of groups of neurons in the patient's brain.

235. (Currently Amended) The method of claim 227~~231~~, further comprising storing the patient's response to the first neural modulation signal in a memory device.

236. (Currently Amended) A method of managing epilepsy, comprising:
monitoring parameters of a patient's brain activity to predict an onset of a seizure;
delivering a first neural modulation signal to the patient when the monitored parameters of a patient's brain activity indicate undesirable brain activity that is predictive of the onset of a seizure;
monitoring a patient's brain activity response after delivering the first neural modulation signal;

The method of claim 227, comprising deriving parameters of the ~~a~~ second neural modulation signal from the patient's brain activity response to the first neural modulation signal.

delivering the second neural modulation signal to the patient if the monitored brain activity response indicates that said patient's brain activity is undesirable.

237. (Currently Amended) The method of claim 227236, wherein at least one of the first and second neural modulation signals comprises medication.

238. (New) The method of claim 212 wherein delivering the neural modulation signal and delivering the subsequent neural modulation signal comprise delivering the signal to a peripheral nerve.

239. (New) The method of claim 212 wherein measuring one or more signals from a patient's brain comprises using at least one intracranial electrode.

240. (New) The method of claim 212 wherein the neurological or psychiatric disease is epilepsy and the future symptomatology is a seizure.